

# EUROPEAN PHARMACOPOEIA

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## 5.11. CHARACTERS SECTION IN MONOGRAPHS

The General Notices indicate that the statements included in the Characters section are not to be interpreted in a strict sense and are not requirements. For information of users, the methods recommended to authors of monographs as the basis for statements concerning hygroscopicity, crystallinity and solubility are given below.

### HYGROSCOPICITY

This method is to be carried out on a substance that complies with the test for loss on drying or water content of the monograph. The method gives an indication of the degree of hygroscopicity rather than a true determination.

Use a glass weighing vessel 50 mm in external diameter and 15 mm high. Weigh the vessel and stopper ( $m_1$ ). Place the amount of substance prescribed for the test for loss on drying or water in the vessel and weigh ( $m_2$ ). Place the unstoppered vessel in a desiccator at 25 °C containing a saturated solution of ammonium chloride or ammonium sulphate or place it in a climatic cabinet set at  $25 \pm 1$  °C and  $80 \pm 2$  per cent relative humidity. Allow to stand for 24 h. Stopper the weighing vessel and weigh ( $m_3$ ).

Calculate the percentage increase in mass using the expression:

$$\frac{m_3 - m_2}{m_2 - m_1} \times 100$$

The result is interpreted as follows:

- *deliquescent*: sufficient water is absorbed to form a liquid,
- *very hygroscopic*: increase in mass is equal to or greater than 15 per cent,
- *hygroscopic*: increase in mass is less than 15 per cent and equal to or greater than 2 per cent,
- *slightly hygroscopic*: increase in mass is less than 2 per cent and equal to or greater than 0.2 per cent.

### CRYSTALLINITY

This method is employed to establish the crystalline or amorphous nature of a substance.

Mount a few particles of the substance to be examined in mineral oil on a clean glass slide. Examine under a polarising microscope. Crystalline particles exhibit birefringence and extinction positions when the microscope stage is revolved.

### SOLUBILITY

For this test a maximum of 111 mg of substance (for each solvent) and a maximum of 30 ml of each solvent are necessary.

#### Dissolving procedure

Shake vigorously for 1 min and place in a constant temperature device, maintained at a temperature of  $25.0 \pm 0.5$  °C for 15 min. If the substance is not completely dissolved, repeat the shaking for 1 min and place the tube in the constant temperature device for 15 min.

#### Method

Weigh 100 mg of finely powdered substance (90) in a stoppered tube (16 mm in internal diameter and 160 mm long), add 0.1 ml of the solvent and proceed as described under Dissolving Procedure. If the substance is completely dissolved, it is *very soluble*.

If the substance is not completely dissolved, add 0.9 ml of the solvent and proceed as described under Dissolving Procedure. If the substance is completely dissolved, it is *freely soluble*.

If the substance is not completely dissolved, add 2.0 ml of the solvent and proceed as described under Dissolving Procedure. If the substance is completely dissolved, it is *soluble*.

If the substance is not completely dissolved, add 7.0 ml of the solvent and proceed as described under Dissolving Procedure. If the substance is completely dissolved, it is *sparingly soluble*.

If the substance is not completely dissolved, weigh 10 mg of finely powdered substance (90) in a stoppered tube, add 10.0 ml of the solvent and proceed as described under Dissolving Procedure. If the substance is completely dissolved, it is *slightly soluble*.

If the substance is not completely dissolved, weigh 1 mg of finely powdered substance (90) in a stoppered tube, add 10.0 ml of the solvent and proceed as described under Dissolving Procedure. If the substance is completely dissolved, it is *very slightly soluble*.